The Fertilizer Institute

Nourish, Replenish, Grow

William C. Herz
Director of Scientific Programs

April 4, 2003

VIA FIRST CLASS MAIL, E-FILE, FAX

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: NPRM Regarding the Registration of Food Facilities

Dear Sir or Madam:

The Fertilizer Institute (TFI), on behalf of its member companies, submits these comments in response to the Food and Drug Administration's (FDA's) notice of proposed rulemaking (NPRM) regarding the registration of food facilities, entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." This NPRM was published in the *Federal Register* on Feb. 3, 2003 (68 Fed. Reg. 5378).

Statement of Interest

TFI represents the nation's fertilizer industry. Producers, manufacturers, retailers, trading firms and equipment manufacturers which comprise its membership are served by a full-time Washington, D.C., staff in various legislative, educational and technical areas as well as with information and public relations programs.

Some TFI member company facilities produce animal feed and feed additives and, therefore, these facilities are potentially subject to registration under FDA's NPRM. Further, some TFI member companies hold agricultural commodities for sale and may be eligible for the exclusion from reporting for retail facilities. As such, TFI and its members have a substantial interest in this rulemaking.

TFI's Comments

At the outset, TFI encourages FDA to implement its regulations far enough in advance of the Dec. 12, 2003, registration date specified in the act to allow affected facilities the opportunity to understand the registration scope and to be in a position to file timely registrations. TFI's comments on the NPRM are included below.

02N-0278

C186

Union Center Plaza
820 First Street, NE Suite 430
Washington, DC 20002

202.962.0490
202.962.0577 fax
www.tfi.org

A. FDA should develop a single registration form for companies with multiple facilities that are subject to registration.

In the NPRM, FDA requires owners, operators or agents in charge of either a domestic or foreign "facility" to register if such a facility is engaged in the manufacturing, processing, packing or holding of food for consumption in the United States. 68 Fed. Reg. at 5417 (21 C.F.R. § 1.225(a)). A facility is defined as "any establishment, structure or structures under one management at one general physical location or, in the case of a mobile facility traveling to multiple locations that manufactures, processes, packs or holds food for consumption in the United States." *Id.* at 5418 (21 C.F.R. § 1.227(b) (2)). Under this definition, a company with several food manufacturing locations in the United States would have to ensure that each facility registers.

To facilitate the registration process, TFI encourages FDA to recognize, as an alternative to single facility registration, a registration form for a corporate parent to complete that would identify all facilities owned, operated or controlled by that parent that are subject to registration. This would allow greater coordination and would also decrease the paper burden on FDA.

B. Fertilizer does not meet the definition of a food.

The key to reporting is whether a facility manufactures, processes, packages or holds food for consumption in the United States. "Food" is defined as "fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients; infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy and canned food." 68 Fed. Reg. at 5418 (21 C.F.R. § 1.225(b)(4)). Some TFI member companies manufacture animal feed and ingredients/additives for animal feed. As to these members, it is appears that FDA's registration program, when finalized, will subject them to registration.

It does not appear, based on our review of the definition of "food," that the manufacturer of a fertilizer for use in the United States would be subject to this registration requirement. Fertilizer is not specifically identified in the definition of "food" and the examples given do not provide support for a conclusion that fertilizer is a "food." TFI's seeks FDA's confirmation of our conclusion.

As previously mentioned, some TFI members manufacture fertilizer that may be sold and then utilized within blending facilities as feed additives. These fertilizers may have other uses (*e.g.*, as a feed additive) and the manufacturer may not know what the use will be for the product, as produced. It would appear, based on the proposed regulatory language, that a manufacturer of a material that may meet the definition of food is not required to register unless that manufacturer knows that the material is going to be consumed in the United States as food. In the example provided above, unless the feed additive manufacturer knows that the feed additive will be used for consumption in the United States, registration would not be required. We seek FDA's concurrence with our conclusion.

C. An agricultural facility selling animal feed to farmers should be exempt from registration as a "retail" facility.

In the fertilizer and animal feed/feed additive distribution chain, feed/feed additives are frequently distributed to small agricultural facilities in rural America where these materials are sold to farmers and other end users. At times, these agricultural facilities may mix, blend or react these materials at the request of the end user, or may repackage the bulk materials in other containers.

Under FDA's NPRM, those manufacturing/processing, packing, or holding foods for consumption in the United States are subject to registration; however, an exemption from registration is provided for "retail facilities". 68 Fed. Reg. at 5417 (21 C.F.R. § 1.226(c)). A "retail facility" is defined as "a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries. The term includes facilities that not only sell food directly to consumers, but that also manufacture/process food in that facility solely for direct sale to consumers from that same facility." *Id.* at 5418 (21 C.F.R. § 1.227(b)(11)).

This definition is confusing in several respects. First, must a facility sell 100 percent, 51 percent, or some other percent of its food products directly to consumers to be eligible for the exclusion? Second, in the case of animal feed/feed additives, what is meant by the term "consumers", which is not defined in the regulations?

We encourage FDA, in its final rule, to adopt a definition of a retail facility that is consistent with the definition adopted by the U.S. Occupational Safety and Health Administration (OSHA) with respect to its Process Safety Management Standard (PSM Standard), found at 29 C.F.R. § 1910.119. OSHA excludes from coverage under the Standard "retail facilities" and defines such a facility as "an establishment that would otherwise be subject to the PSM standard at which more than half of the income is obtained from direct sale to end users." Memorandum from John B. Miles, Jr., OSHA director directorate of compliance programs, to Richard S. Terrill, OSHA acting regional administrator Region X (November 8, 1995). Such a definition is easy to apply.

Should FDA not adopt our proposed definition, then we seek FDA's concurrence that a farmer or other end user of animal feed/feed additives is a "consumer" for purposes of the retail exclusion and that sales of at least 50 percent of such feed/feed additives to an end user is sufficient for the facility to quality as a retail facility.

Conclusion

TFI is pleased to submit these comments. Should you have any questions regarding our comments, please contact me by telephone at (202) 515-2706.

Sincerely yours,

William C. Herz
Director, Scientific Programs

The Fertilizer Institute

Nourish, Replenish, Grow

FACSIMILE TRANSMITTAL

TO: FDA E-Dockets

FROM: William C. Herz, Director of Scientific Programs

SUBJECT: Comments on HFA-305, NPRM Registration of Food Facilities

DATE: April 4, 2003

PAGES: 5

Please accept these comments on the NPRM published in the *Federal Register* on Feb. 3, 2003 (68 Fed. Reg. 5378).

Union Center Plaza
820 First Street, NE Suite 430
Washington, DC 20002

202.962.0490
202.962.0577 fax
www.tfi.org